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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/883,119 | 06/14/2001 | Andrew D. Ellington | TEXAS-11147 | 8203 |
| 23535 7590 04/09/2007 MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105 | | | EXAMINER EPPS FORD, JANET L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 04/09/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/883,119

Applicant(s)

ELLINGTON ET AL.

Examiner

Janet L. Epps-Ford

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-14 and 128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-14 and 128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-22-07 has been entered.

Sequence Listing Compliance

2. Claims 1 and 128 are objected to for failing to recite the appropriate sequence identifiers. According to 37 CFR 1.821 through 1.825, Applicants are required to assign a sequence identifier (SEQ ID NO) for every disclosed unbranched nucleic acid sequence of 10 or more nucleotides and list these sequences individually in a Sequence Listing as a separate part of the disclosure. The Sequence Listing submitted 1-29-07, does not include the sequence recited in the instant claims, specifically: 5'-GGACCUC-GGCGAAAGC-N50-GAGGUUAGGUGCCUCGUGAUGUCCAGUCGC-3', where N is any nucleotide." Applicants have amended the claims to recite "SEQ ID NO: 67" however this sequence is not the same as the sequence set forth in the instant claims. 37 CFR 1.821(d) states: Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, *reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims,*

even if the sequence is also embedded in the text of the description or claims of the patent application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 9-14 and 128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New Matter/ Written Description.

(1) The instant claims were amended to assign the sequence identifier SEQ ID NO: 67 to the sequence set forth in the instant claims: 5'-GGACCUCGGCGAAAGC-N50-GAGGUUAGGUGCCUCGUGAUGUCCAGUCGC-3' (SEQ ID NO: 67), where N is any nucleotide. However, according to the Sequence Listing filed 1-29-07, SEQ ID NO: 67 has the following sequence: ggaccucggcgaaagcnnnnnnnnnnnnnnnnnnnnnnnnnnnnnnngagguuaggtgccucgugauguccagucgc, wherein n is a, c, g, t or u. The sequence set forth in the newly added sequence listing comprises a thymidine (t) residue that is not present in the sequence originally set forth in the claims.

Applicant's insertion of SEQ ID NO: 67 into the claims does not find support in the specification as originally filed since the sequence defined in the Sequence listing

filed 1-29-07 does not find support in the specification as originally filed. Applicant's amendment to the claims filed 1-29-07 is considered new matter. Applicants must remove the new matter in response to this Office Action.

(2) Instant claim 1 and 128 recite that the regulatable, catalytically active, polynucleotide having a catalytic domain and a regulatory domain, wherein the catalytic activity of the catalytic domain is regulated by the interaction of **a peptide effector** with the regulatory domain, wherein the catalytic activity is ligation. However, the specification as filed nor the claims provides sufficient description of the amino acid sequence structure of the entire genus of peptide effectors according to the present invention, such that the skilled artisan would be able to immediately envision the structures of all of the members of the claimed genus.

The specification as filed provides a Ligation assay (see paragraph [00167]) to identify peptide effectors of ribozymes. According to the specification as filed the sequence set forth in the claims is based upon the L1 RNA ligase (see Robertson et al. 1999), which is disclosed as regulated by an oligonucleotide effector. Applicants have identified Cyt18 dependent ribozyme ligase, and the hen egg white lysozyme dependent ribozyme ligase, however other than these two structures, there is no correlation between the 50 undefined nucleotides encompassed by the polynucleotide sequence set forth in the instant claims, and its catalytic activity, wherein said catalytic activity is regulated by an undefined peptide effector. The structure of these nucleotides must be identified empirically by further experimentation. See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known

or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” However, the catalytic core used in the method is randomized within the catalytic core region. The structures of each individual catalytic core that is regulated by a peptide effector encompassed by the claimed genus, must be identified empirically. Thus, based upon this observation it is immediately apparent that applicants were not in possession of the full scope of peptide effectors encompassed by the instantly claimed invention.

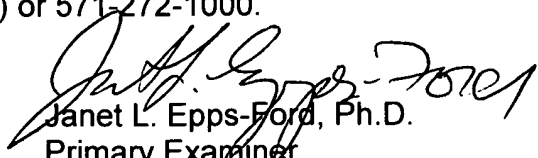
See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, “Written Description” Requirement. These guidelines state: “[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE